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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/531,822  | 10/24/2005  | Mark Brister         | PA1187              | 3938             |
| 28390 7590 05/27/2010<br>MEDTRONIC VASCULAR, INC.<br>IP LEGAL DEPARTMENT<br>3576 UNOCAL PLACE<br>SANTA ROSA, CA 95403 |             |                      |                     |                  |
| EXAMINER<br>HOUSTON, ELIZABETH  |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 3731  |             |                      |                     |                  |
| NOTIFICATION DATE   |             | DELIVERY MODE        |                     |                  |
| 05/27/2010  |             | ELECTRONIC           |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

### Office Action Summary

**Application No.**

10/531,822

**Applicant(s)**

BRISTER, MARK

**Examiner**

ELIZABETH HOUSTON

**Art Unit**

3731

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 March 2010.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-6 and 8-25 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1, 3-6 and 8-25 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/GS/US)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/29/10 has been entered.

### ***Claim Objections***

2. Claims 1 and 6 are objected to because of the following informalities: Claims 1 and 6 recite "the first coating *section* is disposed on and completely covers the outer surface" and "the second coating *section* is disposed on and completely covers the outer surface". Stating that a *section* is disposed on a portion of the stent is awkward. Applicant is respectfully asked to verify whether this was applicant's intention or not. With respect to the other claims, examiner believes it more appropriate to recite --- *the first coating is disposed on* ----. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

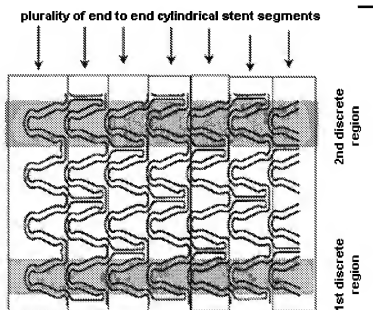
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**4. Claims 1, 3-6 and 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Castro et al (US 6,616,765).**

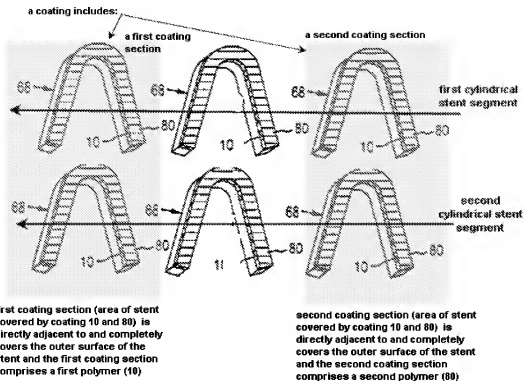
5. Regarding claims 1 and 6, Castro discloses the invention substantially as claimed comprising a catheter, a balloon operably attached to the catheter, and a stent disposed on the balloon (col. 1, lines 19-27). The stent has a plurality of end to end longitudinally adjacent cylindrical stent segments (See Fig. 6a), the axis of the stent segments lying along a longitudinal axis. The stent has a first and second region continuous over at least one pair of adjacent cylindrical segments (see below). A coating (10 and 80 combined) including a first coating section (see below; note that the claim does not preclude the first coating section from comprising more than one coating) comprising a first polymer (for example 10) and a second coating section (see below; note that the claim does not preclude the second coating section from comprising more than one coating) comprising a second polymer (80), the first polymer being different than the second polymer (C17:L61-C18:L5); wherein the first coating section is directly adjacent to and completely covers the outer surface of the longitudinally adjacent cylindrical stent segments in the first region [note that the claim requires the “coating section” be adjacent to the outer surface not the “coating” and that the coating section includes both coatings 10 and 80, since the claims does not

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preclude the coating section from having more than one coating]; and the second coating section is directly adjacent to and completely covers the outer surface of the longitudinally adjacent cylindrical stent segments in the second region [note that the claim requires the “coating section” be adjacent to the outer surface not the “coating” and that the coating section includes both coatings 10 and 80, since the claims does not preclude the coating section from having more than one coating]. The first region and second region are discrete, and the first coating section and second coating section are discrete. [See marked up figures below where the first figure is the stent as a whole (Fig. 6a) denoting the cylindrical sections or rings of the stent and the second figure is stent formation put together to show how a stent would appear with the coating arrangement depicted in Fig. 14b.]



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6. Regarding claims 3, 4, 8, and 9, Castro discloses that the first coating section includes a first therapeutic agent (10) and that the second coating section includes a second therapeutic agent (80) (col. 17, line 64 – col. 18, line 2).
7. Regarding claims 5 and 10, Castro discloses that the first and second regions can form a striped, spotted or ring pattern (see above depicting a striped pattern and note that the choosing of regions is subjective and not limited by the claims).

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**9. Claims 11-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al (US 6,616,765) in view of Ragheb (US 5,873,904).**

10. Regarding claim 22, Castro discloses a stent having a plurality of cylindrical segments (78) having a first discrete region and a second discrete region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments (see figures above), a first polymer including a first therapeutic agent (10) and a second polymer including a second therapeutic agent (80), the first polymer being different from the second polymer (C17:L61-C18:L5).

11. Castro does not explicitly disclose the first polymer being directly adjacent to the outer surface of the stent as a first coating section and the second polymer being directly adjacent to the outer surface of the stent as a second coating section. However Ragheb discloses a coated stent that incorporates the concept of applying coatings in different patterns including applying in parallel lines, particularly where two or more bioactive material are applied to the same surface indicating a first coating section being discrete from a second coating section. Since Castro depicts many different variations of drug coating patterns (see 7a-16b), it would have been obvious to one having ordinary skill in the art at the time of the invention to apply the teachings of Ragheb to incorporate a pattern that includes distinct parallel lines for each material such that each material is adjacent to the outer surface of the stent and each coating section is discrete.

12. Castro does not explicitly disclose that the first region has a longitudinal length greater than the diameter of the stent in an expanded stent. However, it would be obvious to vary the length of the stent and the diameter of the stent to result in a stent where the length is greater than the diameter, since it is well known that the length and diameter will need to be varied depending on where the stent is intended to be delivered. Since the first regions can extend the length of the stent as depicted above, and the length can be modified to be greater than the diameter of the stent, the modified Castro will have a region that has a longitudinal length greater than the diameter of the stent in an expanded state. Since applicant failed to traverse examiner's assertion, the common knowledge or well-known in the art statement is taken to be admitted prior art (MPEP 2144.03 C).

13. Regarding claim 23, modified Castro does not explicitly disclose that the first region and the second region are separated by a bare section. However both Castro and Ragheb disclose various configurations that incorporate more than one coating as state above. Ragheb further discloses that portions of the stent would not be coated (C19:L64-67). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate bare sections of stent in between coated sections as suggested by Ragheb. Doing so would provide the advantage of providing drug to certain parts of the vessel (such as near a lesion) while not providing drug to another part of the vessel (such as near healthy tissue). A person of ordinary skill has good reason to pursue the known options within his or her technical grasp if it yields predictable results.



Regarding claims 24 and 25, Castro discloses the invention substantially as claimed above except for exact dimensions of the bare section. It would have been obvious to one having ordinary skill in the art at the time the invention was made to vary the size of the bare section based on the size of the vessel and size of the lesion being treated. It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch* 617 F.2d 272,205 USPQ 215 (CCPA 1980). A person of ordinary skill has good reason to pursue the known options within his or her technical grasp if it yields predictable results.

14. Regarding claims 11 and 18, Castro further discloses mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution (col. 11, lines 7-13), applying the first polymer solution to the first region to form a first coating section of a coating completely covering the outer surface of the longitudinal adjacent cylindrical stent segments in the first region (col. 14, lines 65-67), mixing a second polymer and second therapeutic agent with a solvent to form a second polymer solution (col. 17, line 62 – col. 18, line 4), and applying the second polymer solution to the second region to form a second coating section of the coating completely covering the outer surface of the longitudinal adjacent cylindrical stent segments in the second region (col. 18, lines 14-32). The modification taught by Ragheb above incorporates the step of applying the first polymer solution directly to the stent in the first region and applying the second polymer solution directly to the stent in the second region.

15. Castro fails to specifically disclose that the solvent mixed with the second polymer and second therapeutic agent is a second solvent, but teaches that it could be

a second solvent (col. 11, lines 55-59; col. 12, lines 20-24). Choosing a solvent based on the polymer chosen implies that if a second polymer is used, then a second solvent will also be used. Further, Castro discloses that all other variables of the second composition are different than that of the first, so it would have been obvious to choose a second solvent when forming the second polymer solution. Since applicant failed to traverse examiner's assertion, the common knowledge or well-known in the art statement is taken to be admitted prior art (MPEP 2144.03 C).

16. Regarding claims 12 and 19, Castro further discloses the first and second polymer solutions may be applied simultaneously (col. 17, lines 61-64). Regarding claims 13 and 20, Castro discloses curing the first and second polymer solutions (col. 9, lines 64-65). Regarding claims 14 and 21, Castro further discloses mounting the stent in a coating fixture and spraying the first polymer solution on the first region (col. 6, lines 24-35). Regarding claims 15-17, Castro further discloses mounting the stent in a coating fixture which is a computerized numerically controlled machine (column 7, lines 12-36), and spraying the first polymer solution on the first region by spraying, inkjet spraying, or inkjet printing (column 7, lines 42-45).

### ***Response to Arguments***

17. Applicant's arguments filed 03/29/10 have been fully considered but they are not persuasive. With respect to the 102 rejection under Castro, examiner stresses the point that was depicted above that the claims merely require the "coating section" be adjacent

the outer surface of the stent. The claims are not limited to requiring that the coating itself be adjacent the outer surface.

18. Applicant's arguments with respect to claims 11-25 have been considered but are moot in view of the new ground(s) of rejection. Note that the new grounds of rejection are based on these claims specifically requiring that the "coating" (rather than the "coating section") be adjacent to the stent surface.

### ***Conclusion***

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth Houston/  
Examiner, Art Unit 3731  
05/23/10